

Berlin Heart[®] EXCOR[®]

Pediatric Ventricular Assist Device (VAD)

H100004

Pediatric Advisory Committee
Panel Meeting
2017



Berlin Heart[®] EXCOR[®]

Update

- December 16, 2011
 - **HDE Approval**
 - Pediatric use and allowed to make profit
 - Mandated annual safety review at the PAC
- June 6, 2017
 - **PMA Approval**
- June 29, 2017
 - **HDE withdrawn**
 - No longer required to have annual safety review at the PAC

